smartLAB® easy nG

Wrist Blood Pressure Monitor for Self-Control

User Manual

Please read this manual thoroughly before first using this device

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I. Introduction

Thank you for using the **smartLAB**®easy nG wrist-cuff blood pressure monitor. With this device you can easily control your blood-pressure values and pulse rate and store the measured data. Please read this manual thoroughly, before first using your **smartLAB**®easy nG wrist-cuff blood pressure monitor.

Normal blood pressure fluctuation

All physical activity, excitement, stress, eating, drinking, smoking and many other activities or factors (including taking a blood pressure measurement) will influence blood pressure value. Because of this, it is mostly unusual to obtain identical multiple blood pressure readings.

Blood pressure fluctuates continually — day and night. The highest value usually appears in the daytime and lowest one usually at midnight. Typically, the value begins to increase at around 3:00 AM, and reaches to highest level in the daytime while most people are awake and active.

Considering the above information, it is recommended that you measure your blood pressure at approximately the same time each day.

Please always relax a minimum of 3 to 5 minutes between measurements to allow the blood circulation in your arm to recover. It is rare that you obtain identical blood pressure readings each time.

Caution

- This device is intended for adult use only
- This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the wrist or for functions other than obtaining a blood pressure measurement
- Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Do not begin or end medical treatement based solely on this device. Please contact physician for treatement advice
- If you are taking medication consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician
- This unit is not suitable for continuous monitoring during medical emergencies or operations
- If the cuff pressure exceeds 40kPa (300mmHg), the unit will automatically deflate. Should the cuff not deflate when pressures exceeds 40kPa

(300mmHg), detach the cuff from the wrist and press the START/STOP button to stop inflation

- To avoid measurement errors, carefully read this manual before using the product
- The equipment is not AP/APG equipment and not suitable for the use in the presence of flammable anesthetic mixture with air or oxygen or nitrous oxide
- The operator shall not touch the battery and the patient simultaneously
- The user must check if the equipment functions safely and check if it is in proper working condition before being used
- The max. temperature for the applied parts can be achieved is 42.5°C under the enviromental temperature of 40°C
- Manufacturer will provide circuit diagrams, component part list, etc when requested
- This unit is not suitable for continuous monitoring during medical emergencies or operations. After the cuff inflated long time, the patient's wrist and fingers will be insufficient, anaesthesia, destanding pain and ecchymosis

- Please use the device under the environment which is provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced
- During the use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential alergic reaction or contact injury
- When the device was used to measure patients who have common arrhythmias such as arterial or ventricular premature beats or arterial liberation, the test result may cause deviation. Please consult your physician about the result
- Please use accessories and detachable parts specified/ authorised by manufacturer. Otherwise, it may cause damage to the unit or danger to the user/patient
- This device is contraindicated for any female subject who may be suspected of, or is pregnant. Besides provided inaccurate readings, the affects of this device on the fetus are unknown

Safety information

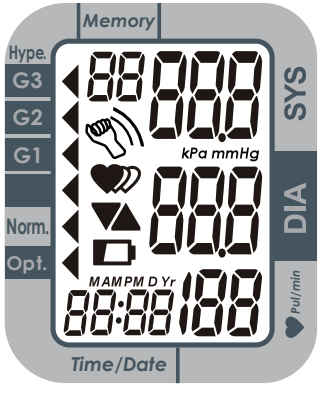
The below signs might be in the user manual, labeling or other component. They are the required for standard and using

	Caution: Consult accompanying documents		Type BF applied part
CE 0537	Symbol for „COMPLIES WITH MDD 93/42/EEC REQUIREMENTS“		DISPOSAL: Do not dispose this product unsorted municipal waste. Collect such waste separately for special treatment is necessary
	Symbol for „MANUFACTURER“		Direct current
	Symbol for „MANUFACTURE DATE“	EC REP	Symbol for „Authorised Representative in the European Community“
SN	Symbol for „SERIAL NUMBER“		

Set Contents

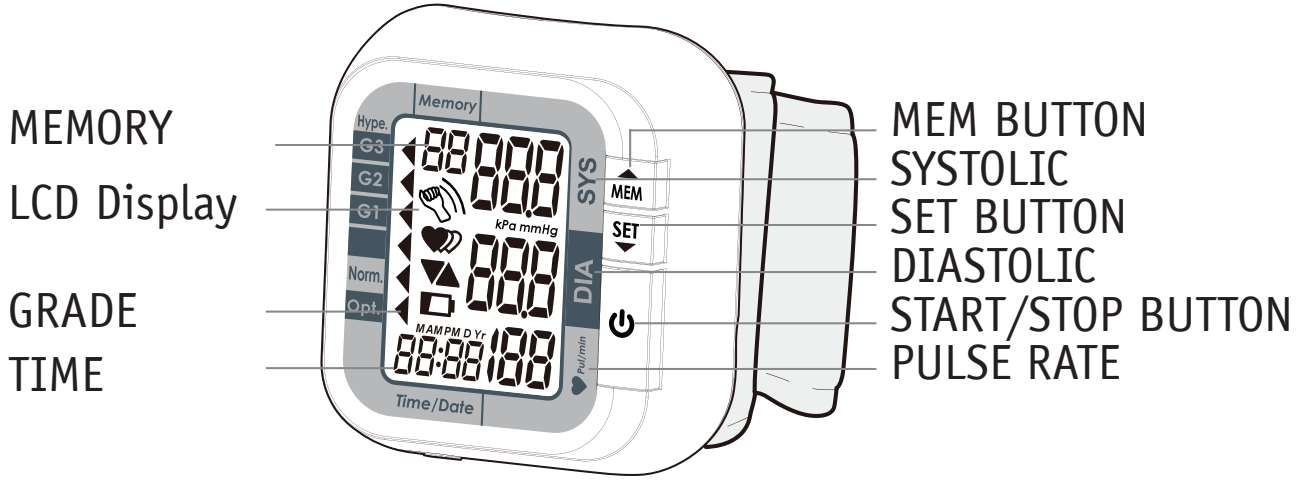
1 smartLAB®easy nG Blood Pressure Monitor
1 User Manual
1 smartLAB® Blood Pressure Passport
2 „AAA“ batteries

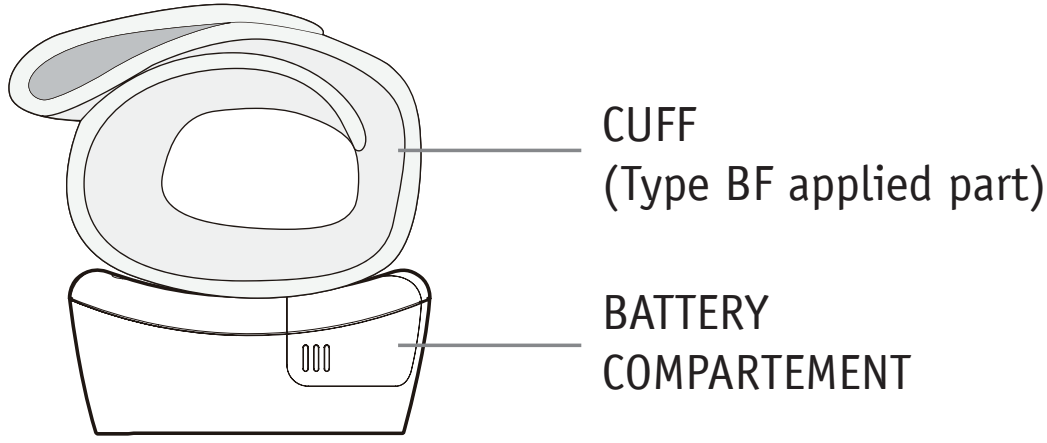
II. Your smartLAB®*easy*
Display & functions



SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High pressure result
DIA	Diastolic blood pressure	Low pressure result
Pul/min	BPM	Pulse/minute; heartbeats/minute
88	Memory	For instructions, refer to Page
	Movement error symbol	Shocking will result in inaccurate values
+Lo	Low battery	Batteries are low and need to be replaced 79
kPa	kPa	Measurement unit of the blood pressure (1kPa=7.5mmHg)
mmHg	mmHg	Measurement unit for blood pressure

SYMBOL	DESCRIPTION	EXPLANATION
▼	Deflating	CUFF air is exhausting or deflating
MAMPM D Yr 88:88	Current time	Year/Month/Day, Hour/Minute
◀	Grade	The grade of the blood pressure
	Arrhyhmia	Irregular heartbeat
	Heartbeat	Heartbeat detection during the measu-erement





Specifications

1. Device: smartLAB®easy nG
2. Size: 68 mm x 75 mm x 31 mm
3. Weight: 120g (without batteries)
4. Measuring mode: Oscillographic testing mode
5. Display Mode: Digital LCD V.A46x33.5mm
6. Device Classification: Internally Powered ME Equipment
7. Memory volume: 60 values
8. Batteries: 2xAAA Alkaline Batteries
9. Measurement range: Rated cuff pressure: 0 kpa - 40 kpa (0mmHg - 300mmHg). Measurement pressure: 4kPa-34kPa (40mmHg - 230mmHg)
10. Measuring accuracy: ± 3 mmHg
11. Heart / Pulse range: 40-199 times/min
12. Pulse accuracy: within ± 5%
13. Environmental temperature for usage: 5°C-40°C
14. Environmental humidity: <80%
15. Storage temperature: -20°C~60°C
16. Environmental storage humidity: 10%-93%
17. Environmental pressure: atmosphere pressure (50-106kPa)

Note:

1. Stay quite, calm and rest for 5 minutes before blood pressure measurement.
2. The cuff should be placed at the same level as your heart.
3. During measurement, neither speak nor move your body and arm.
4. Please measure on same wrist for each measurement.
5. For a meaningful comparison, try to measure under similar conditions. For example, take dialy measurements at approximately the same time, on the same wrist, or as directed by physician
6. Please always relax minimum 3 to 5 minutes between measurements to allow the blood circulation in your arm to recover.
7. Remove the batteries if the monitor will not be used for a month or more to avoid damage of battery leakage.
8. This blood pressure monitor is designed for adults and should never be used on infants or young children. Consult your physician or other health care professionals before use on older children.
9. Blood pressure measurements determined by this monitor are equivalent

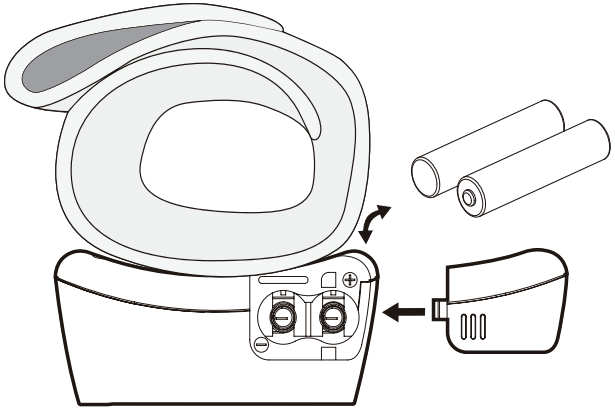
to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard, Electronic or automated sphygmomano-meters.

10. Please avoid strong magnetism interference, such as mobile telephone, microwave oven, etc.
11. Patients with arrhytmia are not supposed to use this device.
12. Up to half an hour before every measurement you should not smoke, eat or do intensive physical exercise.
13. Please stay seated during measurement.
14. Please wear your **smartLAB**®easy nG on the left wrist.

III. Setup & Operating procedures

Installing and Replacing the batteries

- Slide off the battery cover
- Install the batteries by matching the correct polarity, as shown below. Always use the correct battery type (2x AAA alkaline batteries)
- Replace the cover



Replace the batteries when:
- The +Lo shows
- The display dims
- The display does not light up

Remove batteries if the device is not likely to be used for some time

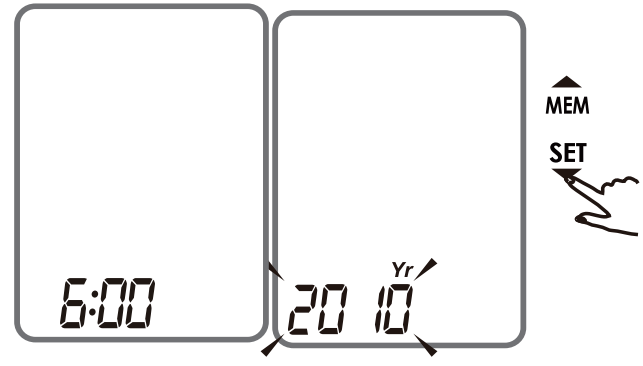
Do not dispose the batteries in fire. Batteries may explode or leak.

The monitor, the batteries and the cuff, must be disposed according to local regulations at the end of their usage.

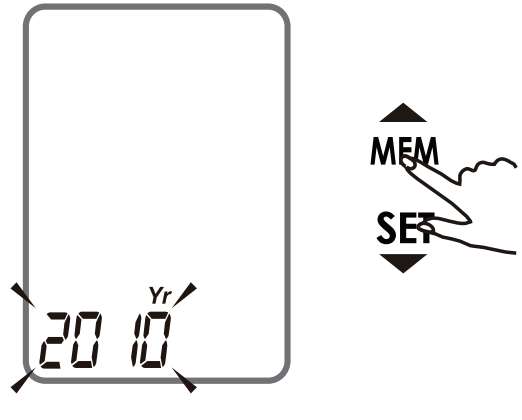
Setting Date, time and measurement unit

It is important to set the clock before using your wrist blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. You need to reset the device after a battery exchange.

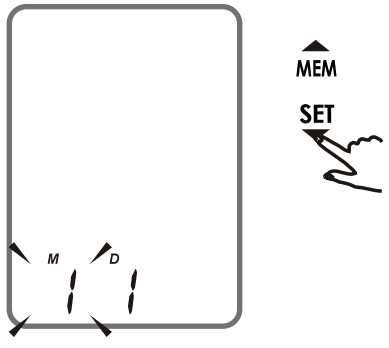
1.When the monitor is OFF, press the SET button to enter the clock mode, then press and hold the “SET” button for 3 seconds to enter year setting



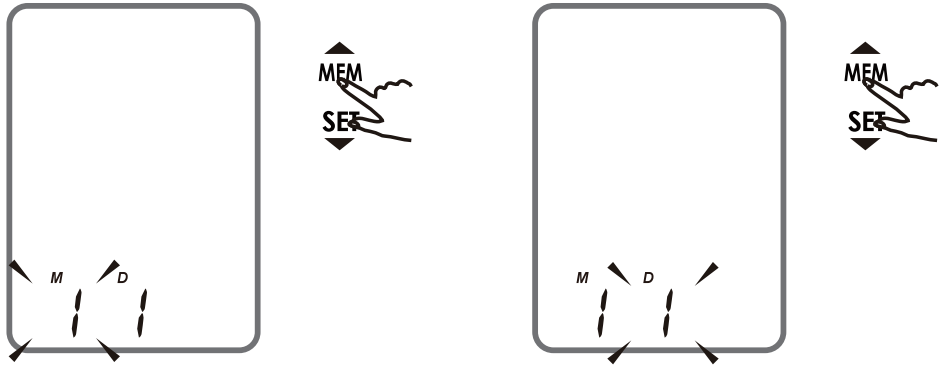
2.Press the “MEM” to change the [YEAR]



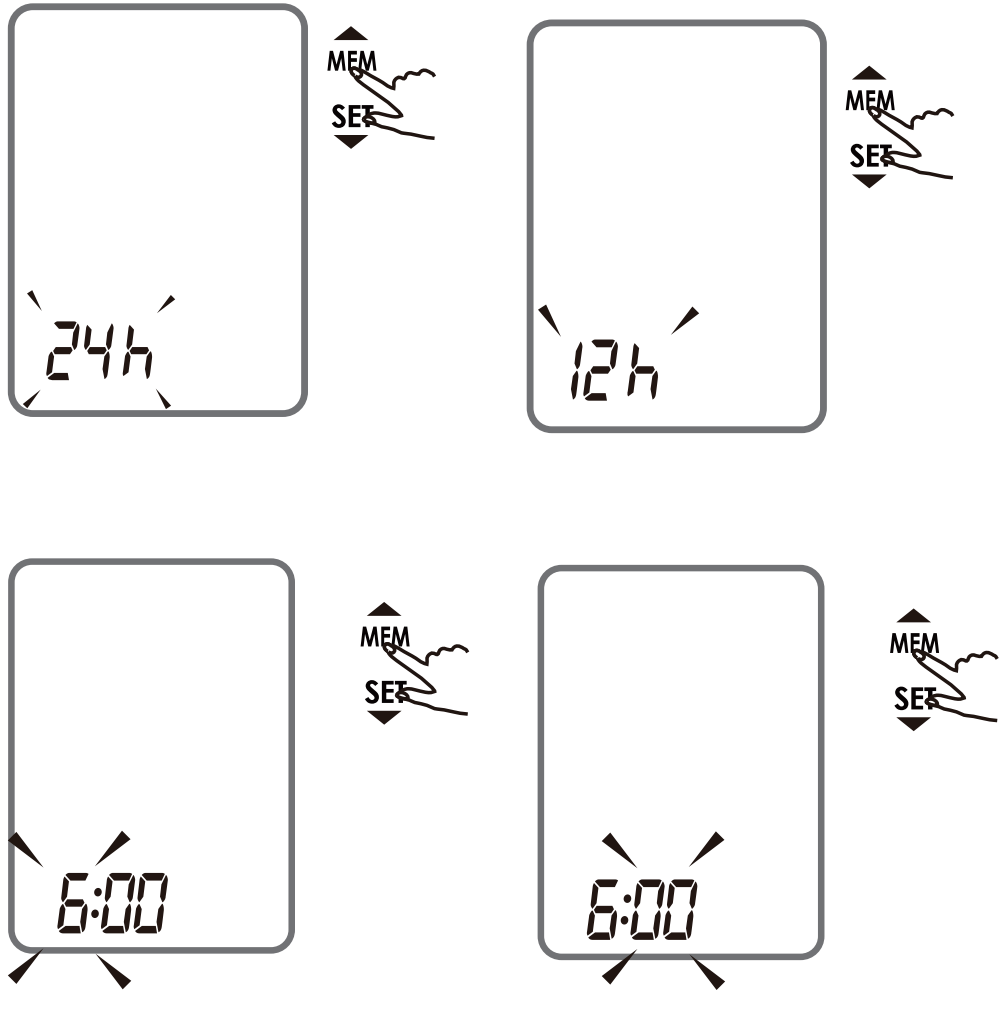
3.When you get the right year, press “SET” to confirm and turn to next step



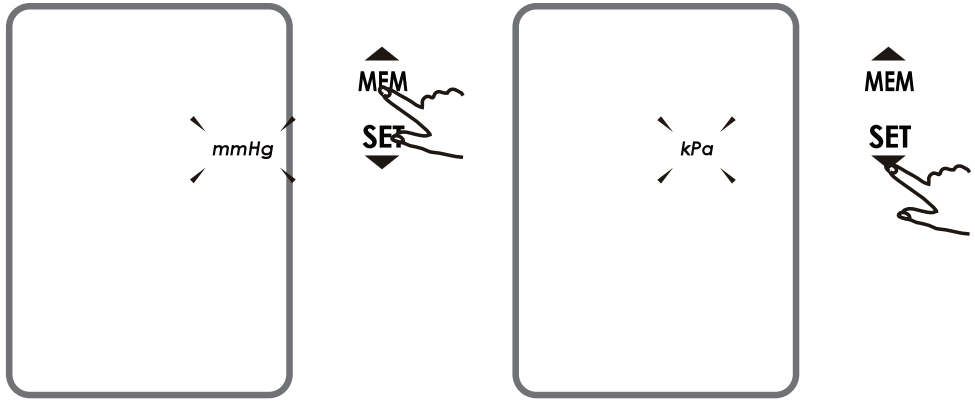
4.Repeat the 2 and 3 to set the [MONTH] and [DAY]



5.Select the 24 hours time form or the 12 hours time form. Repeat step 2 and 3 to confirm [HOUR] and [MINUTE]



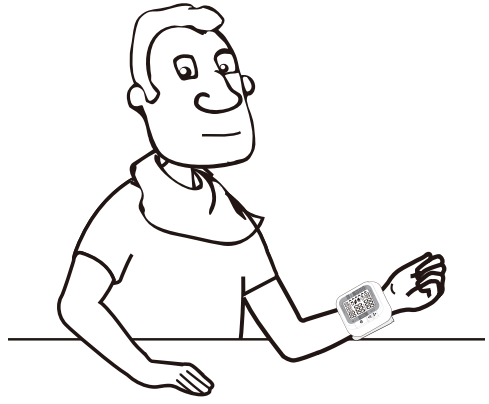
6.Repeat the 2 and 3 to set the [UNIT].



7.After confirming the meausrement unit, the LCD will display all the settings you have done one by one and the monitor will shut off.

Applying the cuff

1. Remove all accessories (watch, bracelet, etc.) from your wrist. If your physician has diagnosed you with poor circulation in your wrist, use the other one.
2. Roll or push up your sleeve to expose the skin.
3. Apply the cuff to your wrist with your palm facing up.
4. Position the edge of the cuff about 1-1.5cm.
5. Fasten the wrist cuff around your wrist, leaving no extra room between the cuff and your skin. If the cuff is too loose, the measurement will not be accurate.



Note:

- Measure on the same wrist each time.
- Do not move your arm, body, or the monitor and do not move the cuff during measurement.
- Stay quiet, calm for 5 minutes before blood pressure measurement.

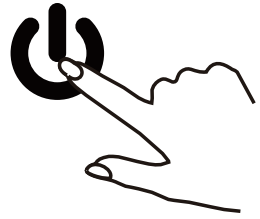
Body posture during measurement

Sitting Measurement – Recommended Position

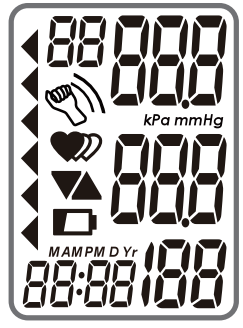
- Sit upright
- Place palm upside in front of you on a flat surface such as a desk or table, with your elbow resting on a chair or table
- The cuff should be at the same level as your heart.
- Place your arm on the monitor's plastic case to maintain a correct and still arm position.

Measuring process

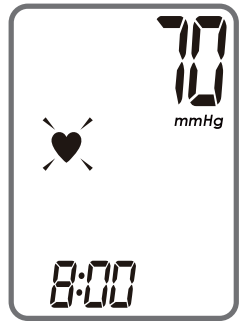
1. When the monitor is off, press the START/STOP to turn on the monitor, and it will finish the whole measurement.



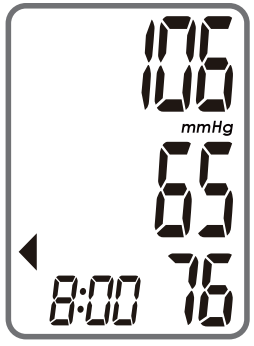
LCD display lights up and all symbols show
Adjust the zero.



While inflating and measuring following will show on display



Results are displayed after measurement and then saved

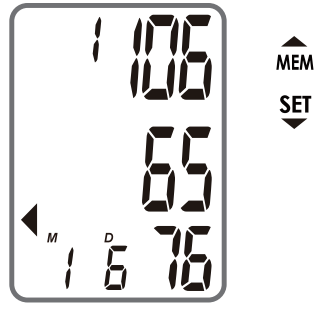


2.Press the START/STOP to turn off the power, otherwise it will turn off within 1 minute.

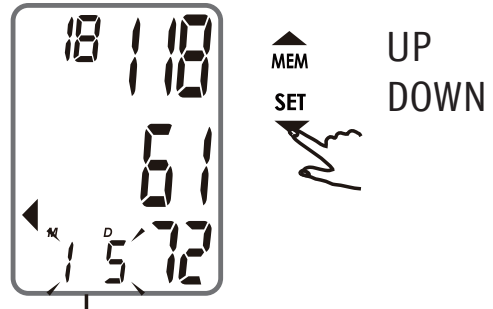
Note: You should wait 3-5 minutes after each measurement to let the blood circulation in your arm recover.
It is unusual to obtain the same values with each measurment. Your constitution is changing minutely and so does our blood pressure level. For this reason it is recommended that blood pressure values must be interpreted on the basis of multiple measurements.

Recall records

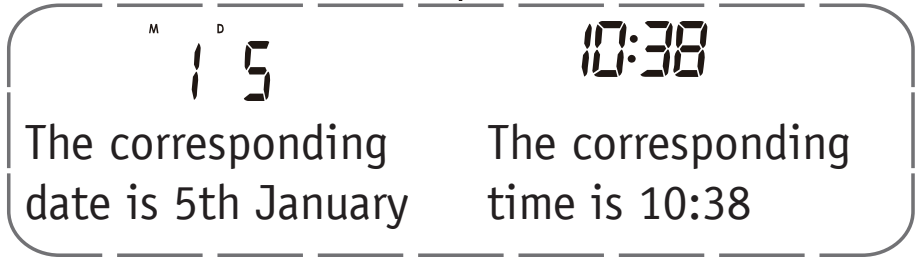
1. When the monitor is off, press the “MEM” to show the first record



2.Press the “MEM” or “SET” to get the record you want



Date and time will display alternately

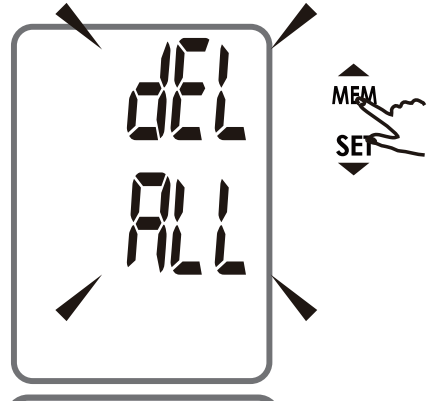


Note: The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g. 2 becomes 3, and so on), and the last record (60) is dropped from the list.

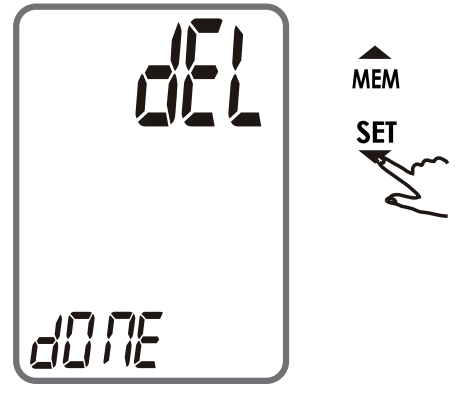
Delete Records

If you want to delet all recorded measurements please follow these steps:

1. When you are in the memory mode, hold pressing “MEM” for 3 seconds, the flash display will show „DEL ALL“

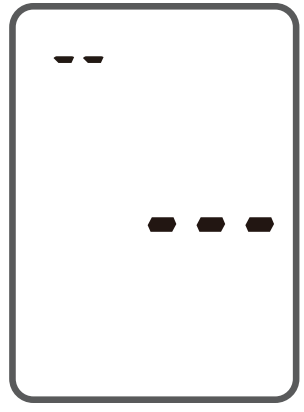


2.Press “SET” to confirm deleting and the monitor will turn off



3.If you don’t want to delete the records, press START/STOP to escape

4.If there is no record the right display will show



Tips for measurement

Incorrect values while measurement can be caused by following circumstances:

- Immediate measurement after eating or drinking
- Immediate measurement after tea, coffee, smoking
- Immediate measurement after talking a bath
- When talking or moving your fingers
- In a very cold environment

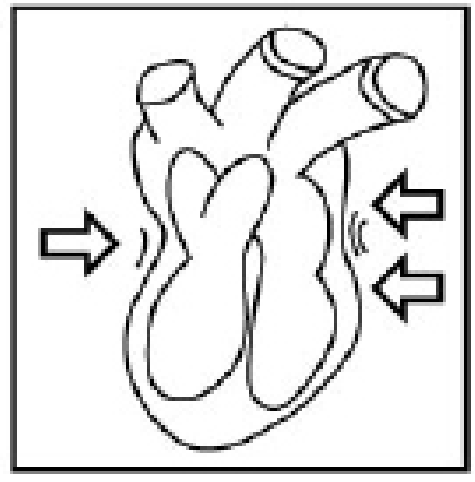
Please also pay attention to following steps when measuring your blood pressure at home:

- The cuff is tied properly
- The cuff should not be to tight or loose
- The cuff is tied on the wrist

Maintenance

- Put in a dry place and avoid sunshine
- Avoid touching water, clean it with a dry cloth in case
- Avoid intense shaking and collision
- Avoid dusty and unstable temperature environment
- Avoid washing the cuff
- If you do not use the monitor for a long time, please remove batteries.
- Clean the cuff with a soft dry cloth. Do not use any abrasive or volatile cleaners.

IV. Miscellaneous



Knowledge on Blood Pressure

Your heart is just like a pump which causes the blood to circulate through all vessels. As a result, the blood pressure is the pressure on the wall of the blood vessel pressed by blood. The output of blood from the heart when it is a systole is called systolic pressure. The blood returning to the heart when it is a diastole is called diastolic pressure.

Blood pressure fluctuates continually — day and night. The highest value usually appears in the daytime and lowest one usually at midnight. Typically, the value begins to increase at around 3:00AM, and reaches to highest level in the daytime while most people are awake and active.

For this reason it is recommended to measure your blood pressure each day at the same time.

Reason / compare to normal BP		systolic pressure		diastolic pressure	
		high	low	high	low
Drinking, smoking		●		●	
Excitement or sporting		●		●	
seeing a doctor, desire to urinate		●		●	
change of temperature	high	●		●	
	low	●		●	
After bathing, deep breathing or yawning		●		●	
Cuff placing	tight		●		●
	loose		●		●
Cuff position	above the heart		●		●
	below the heart	●			●

The blood pressure is influenced by a variety of different factors, such as bodily circumstances or a wrong operation of the monitor. Some people even get nervous when seeing a doctor and that will make their blood pressure rise.

Single measurements can not indicate the whole blood level, so you need not to be anxious for isolated higher or lower blood pressure results. The most important thing is to master one's blood pressure trend through long-term measurement. Please talk to your doctor for useful judgement of your recorded values.

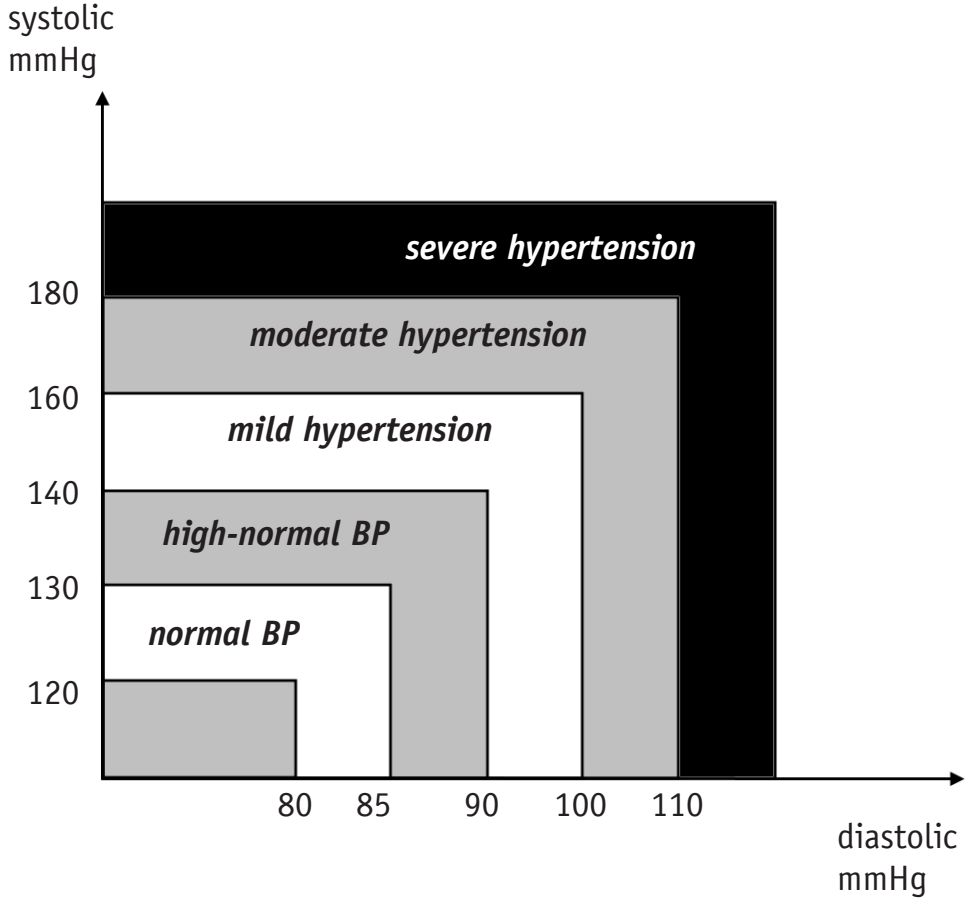
Average values of normal arterial blood pressure (mmHg):

The following chart shows usual average values. You could obtain similar results by measuring your blood pressure for several days at the same time. (so called „Basic Blood Pressure")

Age / Gender	Male		Female	
	systolic	diastolic	systolic	diastolic
11-15	114	72	109	70
16-20	115	73	110	70
21-25	115	73	110	71
26-30	115	75	112	73
31-35	117	76	114	74
36-40	120	80	116	77
41-45	124	81	122	78
46-50	128	82	128	79
51-55	134	84	134	80
56-60	137	84	139	82
61-65	148	86	145	83

Assessing high blood pressure for adults:

The following guidelines for assessing high blood pressure (without regard to age or gender) have been established by the World Health Organization (WHO). Please note that other factors (e.g. diabetes, obesity, smoking, etc.) need to be taken into consideration. Consult your physician for accurate assessment.



Hypertension:

Various cardiovascular or kidney diseases can cause hypertension. Long-term hypertension can also cause pathological changes in heart, brain and kidney. These changes can lead to hypertension complications which are often diagnosed or treated too late.

Low Blood Pressure:

There are two kinds of minimum pressure:

- If you always feel dizzy, unsuitable in the chest and have difficulties in breathing or occurences of temporary myopia when standing up, you might have a standing minimum pressure disease. You should go to see a doctor.
- The original minimum pressure disease has no self-symptoms (besides low blood pressure). To get rid of it, you should pay more attention to nutrition and do more physical exercise.

Troubleshooting

PROBLEM	SYMPTOM	CAUSE	REMEDY
No power	Display is dim or will not light up	Batteries are low	Replace with new batteries
		Batteries are inserted incorrectly	Insert batteries correctly
Low batteries	Show on display	Batteries are low	Replace with new batteries
Error message	E 1 shows	The cuff is not fastend	Refasten the cuff and then measure again
	E 2 shows	The cuff is very tight	Refasten the cuff and then measure again

PROBLEM	SYMPTOM	CAUSE	REMEDY
Error message	E 3 shows	The pressure of the cuff is to high	Relax for a moment and then measure again
	E 10 or E 11 shows	The monitor detected motion while measuring	Movement can effect the measurement. Relax for a moment and then measure again
	E 20 shows	The measurement process does not detect the pulse signal	Loosen the clothing on the wrist and then measure again
	E 21 shows	Incorrect measurement	Relax for a moment and then measure again

PROBLEM	SYMPTOM	CAUSE	REMEDY
Error message	EExx, shows on the display	A calibration error occurred	Repeat the measurement. If the problem persists, contact your retailer for further assistance. Refer to warranty for contact information.

Complied European Standards List

Risk Management	EN/ISO 14971:2007
Labeling	EN 15223-1:2012
User Manual	EN 1041:2008
Generel Requirements for Safety	EN 60601-1:2006/AC2010 EN 60601-1-11:2010
Non-invasive Sphygmomanometers General Requirements	EN 1060-1:1995+A2:2009 EN 1060-3:1997+A2:2009 EN 1060-4:2004
Electromagnetic Compatibility	EN 60601-1-2:2007/AC:2010
Software Lifetime	EN 62304:2006/AC:2008
Usability	EN 60601-1-6:2010 EN 62366:2008

EMC Guidance

Table 1 Guidance and manufacturer's declaration - Electromagnetic Emissions - for all ME Equipment and ME Systems

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic enviroment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	

Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 Guidance and Manufacturer declaration - electromagnetic immunity - for all ME Equipment and ME System

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 4 Guidance and Manufacturer's declaration - electromagnetic Immunity - for ME Equipment and ME Systems that are not Life-Supporting

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic immunity
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Not applicable 3 V/m	Portable and mobile RF communications Equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2,5 GHz

			where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and ***d*** is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$V/m.

Table 6 Recommended separation distance between portable and mobile RF communnications equipment and the ME Equipment or ME System - for ME Equipment and ME Systems that are not Life-Supporting

Recommended separation distances between portable and mobile RF communications equipment and the device.			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = 1.167\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.333 \cdot \sqrt{P}$
0.01	Not applicable	0.117	0.233
0.1	Not applicable	0.369	0.738
1	Not applicable	01.167	2.333

10	Not applicable	3.690	7.378
100	Not applicable	11.67	23.33

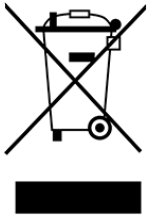
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Safety Notice

WEEE note

The WEEE (Waste Electrical and Electronic Equipment) Directive, that came into effect as European law on 13th February 2003, led to a major change in the disposal of electrical equipment.
The primarily purpose of this directive is to prevent of electronic waste (WEEE),

while encouraging for reuse, recycling and other forms of reprocessing to reduce waste.



The WEEE logo on the product and the packaging indicates that it is not allowed to dispose of the product in the ordinary household waste. It is your responsibility to deliver all the disused electrical and electronic equipment to the respective collection points. A separate collection and proper recycling of electronic waste helps dealing economically with natural resources. Furthermore, the recycling of electrical waste is a contribution to the conservation of our environment and thus the health of all people. More information concerning the disposal of electrical and electronic devices, reprocessing and the collection points
you can get from the local authorities, waste disposal companies, from retailers and manufacturers of the device.

RoHS compliance

This product complies with Directive 2002/95/EC of the European Parliament and the Council of 27th January 2003 regarding the limited use of dangerous substances in electrical and electronic equipment (RoHS) and its variations.

Warranty

HMM Diagnostics GmbH products need to fulfill high quality requirements. Because of this reason, HMM Diagnostics GmbH gives a 2-year warranty by purchasing this **smartLAB**® product. You can even extend the warranty from 3 to 5 years without extra pay when you register your product. Please register online under following website: www.hmm.info/en/registration.

Wear parts, batteries etc. are excluded from warranty.

Hersteller/Manufacturer:

HMM Diagnostics GmbH
Friedrichstr. 89
D-69221 Dossenheim, Germany

E-mail: info@hmm.info
www.hmm.info

Weitere Informationen zu den smartLAB® Produkten /
More information on our smartLAB® products:

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